Docket No. 22956-71
(PATENT)

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Ian D. McRury et al.

Confirmation No. 3998

Application No. 10/024,625

Art Unit: 3731

Filed: December 18, 2001

Examiner: Darwin P. Erezo

For: SUTURE WELDING SYSTEM AND METHOD

I hereby certify that this correspondence is being sent via EFS Web on the date shown below.

Dated: February 11, 2008 Signature: _____
(Ronald E. Cahill)

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLACEMENT APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

I. REAL PARTY IN INTEREST

The real party in interest is Ethicon, Inc. located in Somerville, New Jersey. Ethicon, Inc. derives its rights in this application by virtue of an assignment of the application by the inventors to Ethicon, Inc.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1, 3-8, 20-21, and 23-34 are currently pending in the present application. The Examiner states that claim 8 is withdrawn from consideration. According to the Final Office Action mailed on January 4, 2007, the Advisory Action mailed on March 26, 2007, and the Notice of Panel Decision from Pre-Appeal Brief Review mailed on September 13, 2007, each of claims 1, 3-7, 20-21, and 23-34 stand finally rejected. Accordingly, claims 1, 3-7, 20-21, and 23-34 are subject to this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection. An Pre-Appeal Brief Request for Review was filed with the Notice of Appeal on June 4, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to systems, devices and methods for welding lengths of suture to create a fixed attachment between lengths of suture without tying knots. In particular, the invention provides systems, devices and methods for welding a first length of suture to a second length of suture to create a fixed attachment between the two lengths of suture.

To fully understand the claimed invention, it is first necessary to appreciate the state-of-the-art at the time of the Applicants' invention, which represents the background against which the claimed invention was developed.

A. The Problem Addressed by the Invention is the Difficulty in Forming Knots in Sutures

Many surgical procedures include the use of sutures, particularly for tissue fixation and repair, and often in endoscopic, arthroscopic or other minimally invasive procedures for effecting surgical procedures within a patient's body. Traditionally, once a suture is appropriately positioned with respect to the relevant tissue, the suture ends are knotted together to fix or otherwise repair the tissue. However, knots may be difficult to make, difficult to properly tension and difficult to properly place, particularly in tight spaces. (Page 1, lines 8-17.)

Suture fixation techniques other than knotting, such as frictional welding, have been tried. Frictional welding is generally accomplished by exposing the suture material to ultrasonic energy. Recent examples of this approach are disclosed in patents to Axya Medical, Inc. of Beverly, Massachusetts, including U.S. Patent Nos. 5,417,700; 5,893,880; and 6,174,324; which relate to methods and systems using the application of ultrasonic energy to weld sutures. (Page 1, lines 18-25.) In fact, various Examiners have cited the ultrasonic welding patents of Axya Medical in Office actions during the prosecution of this application (including the citation of US 6,358,271 to Egan et al. in previous Office actions, and the citation of US 6,409,743 to Fenton, Jr. in the outstanding rejection addressed here on appeal). The present inventors have discovered, however, that ultrasonic welding does not work well with all popular suture materials, and proper welding can be sensitive to suture placement and configuration within the welding device. (Page 1, lines 18-27.)

Accordingly, there remains a need to fix sutures without the need to tie knots. In particular, it would be desirable to develop a system to weld lengths of popular suture materials, especially polydioxanone (PDS), a popular suture material for which existing welding methods are insufficient.

B. The Invention Solves the Problem by Providing a Suture Welding System for Fixedly Attaching a First Length of Suture to a Second Length of Suture

The claimed invention allows sutures to be attached without knots by providing systems and methods useful for welding a first length of suture to a second length of suture to create a fixed attachment between the two lengths of suture. In general, the first and second lengths of

suture are welded into a fixed attachment by providing electrosurgical energy (in particular, radio frequency, or RF, electrosurgical energy) to the two lengths of suture. (Page 2, lines 4-15.) FIG. 1 of the application, reproduced below, shows a schematic representation of the suture welding system 10, including an energy source 32 and a suture welding device 12. The suture welding device 12 also includes a suture grasper or suture contacting element 18 on its distal working end. (Page 5, lines 20-26.)

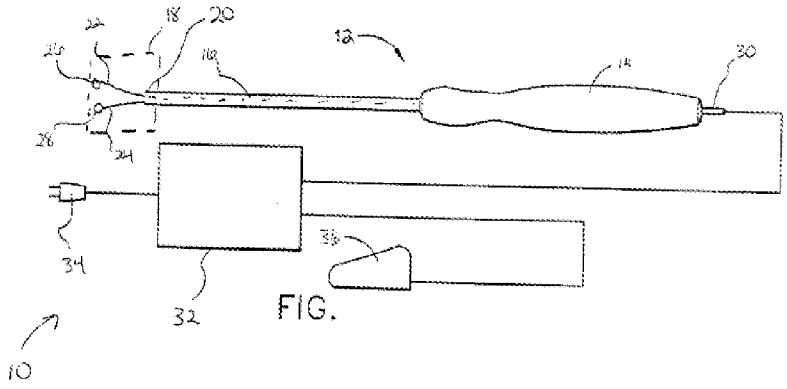

FIG. 1

FIGS. 2A and 2B of the application, reproduced below, show a side view of a suture grasper in open and closed configurations. As illustrated in the Figures, the suture grasper includes a first suture grasping member 150 and second grasping member 152, each of which includes an electrode; 170 and 180 respectively. (Page 8, lines 4-28).

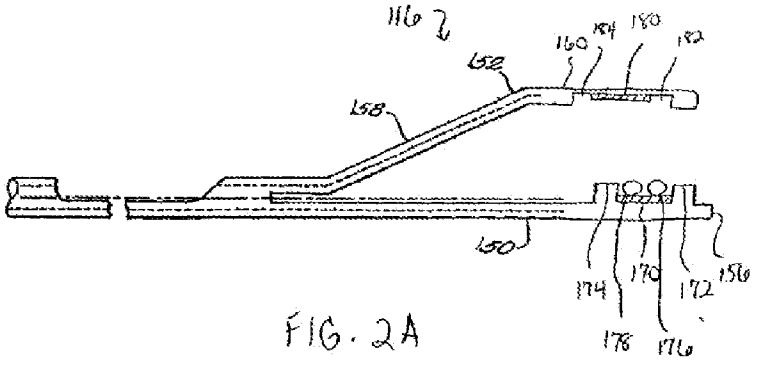

FIG. 2A

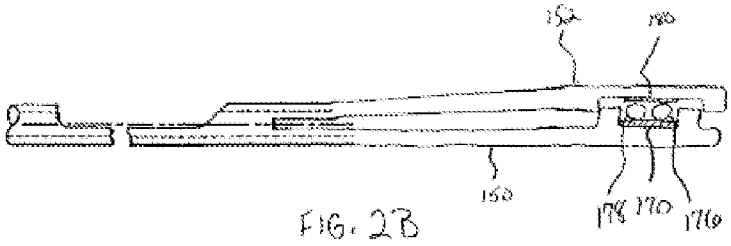

FIG. 2B

Also shown in the Figures are two lengths of suture 176, 178 which are held in contact with the electrodes 178, 180 when the suture grasper 116 is placed in a closed position for welding. (Page 8, line 30 – page 9, line 14.)

FIG. 2C, reproduced below, shows a side view of the suture grasper 116 in a fully closed position with two lengths of suture 176, 178 tightly held within the grasper in close contact with electrodes 170, 180. (Page 9, lines 16-18.)

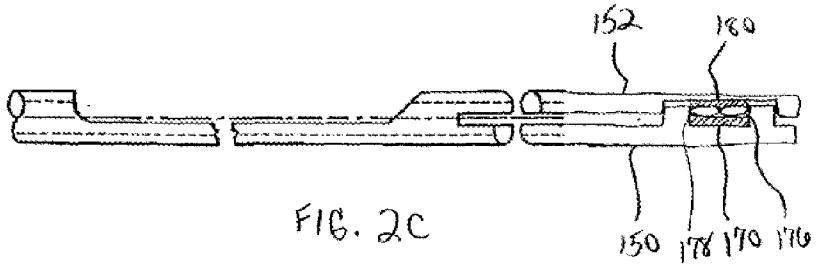

FIG. 2C

Although the lengths of suture 176, 178 are illustrated in FIG. 2C as being deformed due to pressure applied to them by opposed electrodes 170, 180, such deformation may or may not occur depending on the properties of the suture material and the amount of pressure applied. However, it is desirable that there be close physical contact between the electrodes 170, 180 and the lengths of suture 176, 178. (Page 9, lines 18-23.) Electrical energy, preferably in the form of radio frequency or RF energy, can thus be provided to the lengths of suture 176, 178 by the electrodes 170, 180 so as to weld the lengths of suture into a fixed attachment. (Page 2, lines 10-15, and page 6, lines 5-12.)

C. Application of the Principles of the Invention in the Independent Claims

1. Independent Claim 1 Provides a Welding System Using RF Energy for Fixedly Attaching a First Length of Suture to a Second Length of Suture at a Suture Welding Site

Applicant's claim 1 recites a suture welding system 10 for fixedly attaching a first length of suture 176 to a second length of suture 178 at a suture welding site. The system includes an electrosurgical energy source 32 configured to generate radio waves; first and second lengths of suture 176, 178; and a suture welding device 12. (Page 2, lines 4-15.) The suture welding device 12 has a working end 20; a suture contacting element 18 located on the working end 20 and having the first and second lengths of suture 176, 178 disposed thereon (page 5, lines 20-26); a first electrode 26 electrically coupled to the electrosurgical energy source 32 and disposed on the suture contacting element 18 for providing radio frequency energy to the first and second lengths of suture 176, 178 and a second electrode 28 electrically coupled to the electrosurgical energy source 32 and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source. (Page 8, lines 4-28.) Provision of radio frequency energy by the first electrode 26 to the first and second lengths of suture 176, 178 welds the first and second lengths of suture 176, 178 into a fixed attachment. (Page 2, lines 10-15; page 6, lines 5-12.)

2. Independent Claim 20 Provides a Method Using Electrosurgical Energy for Welding a First Length of Suture to a Second Length of Suture to Create a Fixed Attachment Therebetween

Applicant's claim 20 recites a method for welding a first length of suture 176 to a second length of suture 178 to create a fixed attachment therebetween. The method includes providing an electrosurgical energy source 32 and a suture welding device 12. (Page 2, lines 4-15.) The suture welding device 12 has a working end 20; a suture contacting element 18 disposed on the working end 20 (page 5, lines 20-26), the suture contacting element 18 having two opposing faces having a variable gap therebetween, each face having an electrode 26, 28 disposed thereon. (Page 12, lines 22-27.) The first electrode 26 is electrically coupled to the electrosurgical energy source 32 and disposed on the suture contacting element 18 for providing electrical energy to the first and second lengths of suture 176, 178. The second electrode 28 is electrically coupled to

the electrosurgical energy source 32 and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source 32. (Page 8, lines 4-28.) The method also includes placing a first length of suture 176 and a second length of suture 178 into contact with the suture contacting element 18; and providing energy from the electrosurgical energy source 32 through the first electrode 26 to the first and second lengths of suture 176, 178 to weld the first length of suture 176 to the second length of suture 178 to create a fixed attachment therebetween. (Page 2, lines 10-15; page 6, lines 5-12.)

3. Independent Claim 29 Provides a Welding System Using Electrosurgical Energy for Fixedly Attaching a First Length of Suture to a Second Length of Suture at a Suture Welding Site

Applicant's claim 29 recites a suture welding system 10 for fixedly attaching a first length of suture 176 to a second length of suture 178 at a suture welding site. The system includes an electrosurgical energy source 32 and a suture welding device 12. (Page 2, lines 4-15.) The suture welding device 12 has a working end 20; a suture contacting element 18 disposed on the working end (page 5, lines 20-26); a first electrode 26 electrically coupled to the electrosurgical energy source 32 and disposed on the suture contacting element 18 for providing electrical energy to the first and second lengths of suture 176, 178; and a second electrode 28 electrically coupled to the electrosurgical energy source 32 and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source 32. (Page 8, lines 4-28.) The suture contacting element 18 also has at least one pod 172 configured to prevent the first and second sutures 176, 178 from sliding off of the suture contacting element 18. (Page 8, lines 6-10.) Provision of electrical energy by the first electrode 26 to the first and second lengths of suture 176, 178 welds the first and second lengths of suture 176, 178 into a fixed attachment. (Page 2, lines 10-15; page 6, lines 5-12.)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Examiner states that claims 1, 3-7, 20, 21, and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,409,743 to Fenton, Jr. ("Fenton") in view of U.S. Patent No. 6,010,516 to Hulka ("Hulka").

A. Rejection under 35 U.S.C. 103 (a) of the Claim 1 and Claim 29 "System" Groups of Claims

In the final Office Action, the Examiner stated:

As to claims 1, 3-7 and 27-34, Fenton teaches a welding device for fixedly attaching a first and second lengths of suture teaches a first and second lengths of suture **13**, which can be made from polydioxanone (col. 6, line 63); the device comprising:

-a working end **26**, which is configured to provide a variable gap (adjustable jaws) between an open position or a closed position;

-an energy source or horn **25** connected to a working end **26**;

-a suture contacting element, or collar **1**, located/disposed on the working end during use and having the sutures located therein; wherein the collar is formed from weldable material (col. 6, lines 34-43) and is configured to act as a pod to prevent the sutures from sliding off the working end (Fig. 8A);

-wherein the provision of energy from horn **25** to the working end of the device and into the collar **1**, causes the suture to fuse together (col. 7, lines 3-11).

The main embodiments of the Fenton reference are directed toward the working end being a heating element or an ultrasonic horn. However, Fenton does recite that other well-known techniques, such as optical energy, electrical or RF, can be used to weld the sutures together (col. 4, lines 43-51). Fenton is merely silent with regards to the details of said other known techniques.

On the other hand, Hulka teaches a well known coaptation clamp device that uses RF technology, wherein the device comprises an electrosurgical energy source **12** configured to generate radio frequency waves, and electrodes **22**, which is necessary for completing the bipolar circuit. That is, one electrode would inherently provide the RF energy while the other electrode would inherently return the RF energy in order for the current to flow. Hulka also teaches an RF device that is configured to provide a variable gap that can be selectively adjustable between an open and closed position, and wherein the RF device has a pod in any of the serrated portion shown in Fig. 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Fenton to include the RF technology taught by Hulka since the Fenton reference itself teaches that the device would

work with RF technology and that Hulka is merely being provided to teach a generally well known RF device and its associated structures.

Furthermore, the modification to the device of Fenton would have the working end or jaws **26** act as the electrodes, as taught by Hulka, which would in turn have the suture contacting element or collar **1** be disposed on the jaws **26**.

B. Rejection under 35 U.S.C. 103(a) of the Claim 20 "Method" Group of Claims

In the final Office Action, the Examiner stated:

As for claims 20, 21 and 23-26, the above modification of Fenton also discloses a method of welding a first length of suture and a second length of suture, wherein the modified device is provided; a first and second length of suture is placed into the suture contacting element or collar **1**; and an electrosurgical energy source that provides energy to secure the two loose strands of suture **13** together. Furthermore, as shown in the rejection to the device claims above, the suture welding device can be selectively adjustable between an open position and a closed position. Moreover, the collar **1** serves as a pod to prevent the suture from sliding off the working end.

VII. ARGUMENT

A. Neither Fenton nor Hulka Teaches or Suggests All the Elements Recited by the Claim 1 "System" Group of Claims

Neither Fenton nor Hulka teaches or suggests all the features of independent system claim 1. Claim 1 recites a suture welding device including a suture contacting element having first and second lengths of suture disposed thereon. A first electrode is disposed on the suture contacting element for providing radio frequency energy to weld the first and second lengths of suture into a fixed attachment.

Throughout, Fenton teaches "a fusible collar for securing sutures without knots." *See e.g.* Fenton at Abstract, lines 1-3. Every embodiment disclosed in Fenton includes this fusible collar, and the invention in Fenton is expressly described as residing in the collar. Hulka provides a coaptation clamp device that delivers RF energy only to tissue. Such devices are well known and are recognized by numerous patents cited in the prosecution of the present application. No

portion of the Hulka device contacts sutures, sutures are never disposed on the device, and RF energy is not delivered to sutures.

Accordingly, neither reference, alone or combined, teaches or suggests the recitations of claim 1. In addition, many of the claims that depend from claim 1 recite features not taught or suggested by either Fenton or Hulka for reasons over and above the reasons stated for claim 1.

1. Fenton Fails to Disclose, Teach or Suggest the Recitations of Claim 1 Because Nowhere Does Fenton Teach or Suggest a Suture Contacting Element of A Suture Welding Device Having the First and Second Lengths of Suture Disposed Thereon and Electrodes Disposed on the Suture Contacting Element for Providing Radio Frequency Energy to Weld the First and Second Lengths of Suture

Applicant's claim 1 recites, *inter alia*, a suture welding device including a suture contacting element having first and second lengths of suture disposed thereon. The suture contacting element includes:

- a first electrode . . . for providing radio frequency energy to the first and second lengths of suture
- a second electrode . . . for providing a return electrical energy path to the electrosurgical energy source
- wherein provision of radio frequency energy by the first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment.

Neither Fenton, nor Hulka, nor their combination, discloses, teaches or suggests this combination.

a. Fenton Does Not Disclose or Suggest the Suture Welding System of Claim 1 Because it Does Not Disclose a Suture Welding Device With Electrodes for Providing Energy to Weld First and Second Lengths of Suture

Starting with the Fenton reference, Fenton does not teach a suture welding device with electrodes for providing energy to weld first and second lengths of suture. In Fenton, welding horn 25 melts the fusible collar 1 to bind sutures together. The Examiner's asserted correspondence of features of Fenton to the claim elements shows how far afield Fenton is from

the claimed invention. The failure of these correspondences alone causes the Examiner's *prima facie* case of obviousness to collapse. Further review of the references in subsequent sections of the brief shows that these deficiencies cannot be made up from other references or from knowledge in the art.

FIG. 6 of Fenton is reproduced below with markings indicating the Examiner's characterizations of the elements:

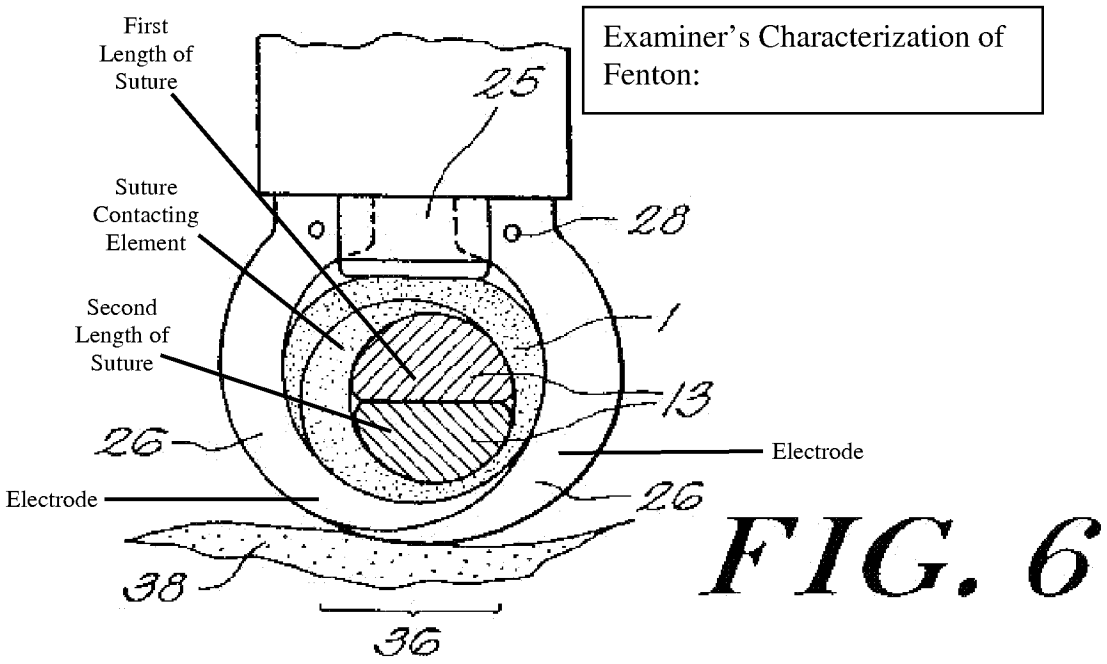

FIG. 6

In the Fenton device, energy is provided by ultrasonic welding horn 25 to melt fusible collar 1 in order to melt the fusible collar onto the sutures and hold them fast. Jaws 26 close over the fusible collar to act as an anvil for the delivery of ultrasonic energy to be effective.

According to the Examiner, the jaws 26 correspond to first and second electrodes. Of course, the jaws are not electrodes and they do not carry any type of electrical energy – in fact, they don't carry any type of energy at all, they act as an anvil. While the Examiner is entitled to give claim language its broadest reasonable interpretation, that interpretation must be reasonable. *See, e.g., In re Buszard*, 2007 U.S. App. LEXIS 22806 (Fed. Cir., September 27, 2007) (Reversing rejection made by Board based upon an unreasonably broad interpretation of the claim term "flexible polyurethane foam reaction mixture" as "any reaction mixture which

produces, at least ultimately, a flexible polyurethane foam.") Here, no person of ordinary skill in the art would read an anvil that carries no electricity as being an electrode.

Still further, Fenton still fails to disclose, teach or suggest providing energy to the lengths of sutures themselves to weld them together. Claim 1 recites a suture contacting element having first and second lengths of suture disposed thereon, and a first electrode disposed on the suture contacting element for ***providing radio frequency energy to the first and second lengths of suture***. In contrast, Fenton only discloses sutures that are wrapped in a fusible collar for loading into an ultrasonic welding device. The Examiner asserts that "the collar/suture contacting element is able to fuse suture together without the collar fusing along with the suture as stated in col. 7, lines 3-11 [of Fenton]." *See* Advisory Action, March 19, 2007. The passage cited by the Examiner merely states that the collar and sutures can be made from materials with different melting points to allow the bonds to occur at various interfaces. Neither this passage, nor any other passage of Fenton, says what the Examiner says it does.

Fenton only discloses applying energy to the collar – never to the suture as is required by the present claims.

b. Fenton Does Not Disclose or Suggest the Suture Welding System of Claim 1 Because it Does Not Disclose Radio Frequency Energy Applied to Sutures

Fenton also does not teach or suggest radio frequency energy applied to sutures. In fact, Fenton teaches away from providing RF energy (as well as any other energy) to the sutures. The Examiner recognizes that Fenton discloses an ultrasonic heating device, but then asserts that "Fenton does recite that other well-known techniques, such as optical energy, electrical or RF, can be used to weld the sutures together (col. 4, lines 43-51)." Fenton does not so recite. In particular, while Fenton does mention radio-frequency energy, ***Fenton would only supply radio-frequency energy to a collar – not to the sutures***.

The actual passages from Fenton that discuss RF energy are as follows:

> The overlapping portions of the collar are adapted to fuse to each other around the elongated members upon ***application of sufficient energy to the overlapping portions of the collar***. . . The energy may be generated from a variety of sources known in the art, such as for example, thermal energy, optical energy, ***radio-frequency energy***, current sources or more preferably, ultrasonic energy. [Column 2, lines 15-39.]
>
> Various methods of fusing or joining sutures or other elongated structures together ***joining by the application of energy to the fusible collar are well known in the art and can be employed to secure the band and sutures***. Examples of such techniques include, but are not limited to, thermal energy (e.g., heat), optical energy (e.g. laser), electrical (e.g., ***radiofrequency RF***), current sources (e.g., resistive heating), and preferably, ultrasonic energy. [Column 4, lines 43-51.]
>
> The ***collar material is preferably also capable of being fused or joined together upon the application of energy***, such as thermal energy (heat), optical energy (laser generated), electrical energy (***radio frequency, RF***), current sources (resistive heating) or, preferably, ultrasonic energy, to the collar. [Column 6, lines 36-39.]

There is no teaching or suggestion to apply RF energy to the sutures. Fenton refers to radio-frequency energy only in the context of application to a fusible collar that is specifically designed for that purpose.

c. Hulka Fails to Fill In the Gaps of Fenton Regarding Claim 1 Because No Portion of the Hulka Device Contacts Sutures, Sutures are Never Disposed on the Device and RF Energy is Not Delivered to Sutures.

Hulka does not disclose, teach or suggest the recitations of claim 1. Hulka provides a coaptation clamp device that delivers RF energy only to tissue. Such devices are well known and are recognized by numerous patents cited in the prosecution of the present application. No portion of the Hulka device contacts sutures, sutures are never disposed on the device, and RF energy is not delivered to sutures.

d. The Combination of Fenton and Hulka Does Not Provide the System of Claim 1

The Examiner suggests two modifications to Fenton. The first is to modify the working end or jaws 26 to act as the electrodes. The second is to modify the device of Fenton to include the RF technology taught by Hulka. Neither Fenton nor Hulka provides a motivation for making the modifications suggested by the Examiner, and even if the modifications were made, the system of claim 1 would still not be taught as there would be no provision of radio-frequency energy to the sutures to weld them together.

Fenton's invention is unmistakable: it is to provide a ***fusable collar*** that surrounds sutures, the fusable collar melting upon the provision of energy so that the sutures are bound by the melted collar material. Other prior art cited in the prosecution of this case (see, for example, U.S. Patent No. 6,358,271 to Egan, and commonly assigned with Fenton, that has been cited in previous office actions in the present application) makes clear that ultrasonic welding is well known and characterized. The advance in Fenton is the provision of the fusable collar.

The Examiner correctly notes that Fenton mentions energy sources other than ultrasonic energy. However, Fenton goes on to make perfectly clear that those energy sources can be used to provide energy to the ***fusable collar***.

A person of ordinary skill in the art combining an RF reference such as Hulka with Fenton would do what Fenton says to do – use the RF energy to melt the ***fusable collar*** of Fenton.

There is no disclosure, teaching or suggestion in Fenton, Hulka, or the combination, to place sutures on an electrode carrying suture contacting element to apply RF energy to the suture material to weld it together. The Examiner can point to none – and none exists.

2. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claims 3 and 4 That the Suture Contacting Element Comprises Two Opposing Faces Having a Variable Gap Therebetween, Each Face of the Suture Contacting Element Having an Electrode Disposed Thereon

Claim 3 recites that it is the suture contacting element (the fusible collar 1 in Fenton, according to the Examiner) that must have two opposing faces having a variable gap therebetween. The two opposing faces must also have an electrode disposed thereon. According to the rejection, the "variable gap," (and thus necessarily the "two opposing faces") are provided by adjustable jaws 26.

Claim 3 is clear that it is the ***suture contacting element that must have two opposing faces having a variable gap therebetween***. The base rejection provides that it is the ***fusable collar that is said by the Examiner to correspond to the suture contacting element*** (indeed, it is the only portion of Fenton that actually contacts the sutures) – however, in rejecting claim 3, the Examiner asserts it is the jaws (which are not the suture contacting element as they never contact the sutures, and which are asserted by the Examiner to be the electrodes) that provide the variable gap.

There is no way to make the Examiner's proposed reading of the prior art disclose, teach or suggest the elements of claims 1 and 3, ***the analogy of the fusible collar to the suture contacting elements does not hold up*** – the fusible collar provides no variable gap.

3. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claims 6 That Sutures Made of Polydioxanone are Welded into a Fixed Attachment

Applicants' claim 6 recites that the first and second lengths of suture that are made of polydioxanone. Although polydioxanone sutures are known, Fenton does not disclose welding of sutures, let alone welding of polydioxanone sutures. The present inventors have found that existing suture welding methods, including the ultrasonic welding disclosed by Fenton, do not work with polydioxanone sutures. For example, the background of the present invention discloses that:

> Suture fixation techniques other than knotting have also been tried. For example, techniques and apparatus for performing frictional suture welding have been disclosed. Such frictional welding is generally accomplished by exposing the suture fixturing and/or **directly exposing the suture material to ultrasonic energy**. U.S. Pat. No. 3,515,848 to Winston et al. discloses devices and methods for ultrasonic suture welding. More recently, patents assigned to Axya Medical, Inc. of Beverly, Mass. (see, e.g., U.S. Pat. Nos. 5,417,700; 5,893,880; 6,174,324) have disclosed devices and methods involving the application of ultrasonic energy to weld sutures. This method, however, **does not work with all popular suture materials, and proper welding can be sensitive to suture placement and configuration within the welding device.**

An express goal of the claimed invention, the first suture welding device of its type, is to employ radio frequency waves in order to facilitate the welding of polydioxanone sutures. Fenton's approach does not address the problems with welding of polydioxanone sutures because Fenton welds a fusible collar instead of welding sutures.

By virtue of its dependence from the independent claim, claim 6 recites that polydioxanone sutures that are welded to each other by the delivery of RF energy through the recited suture welding devices. Fenton does not disclose, teach or suggest such welding. Rather, Fenton teaches that any elongate thing (any suture or any tissue) can be joined together by placing a fusible collar around it.

There is no teaching or suggest anywhere in any cited reference to the successful welding of polydioxanone sutures, and so no disclosure, teaching or suggestion of claim and 6 which supply RF energy to lengths of polydioxanone sutures to weld them to each other.

4. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 8 That the Suture Welding Device Includes a Piston Slidingly Disposed on the Suture Welding Device so as to Be Translatable in a Longitudinal Direction to Move the First and Second Lengths of Suture into Contact With at Least One Electrode

Claim 8 recites that the suture welding device includes a piston slidingly disposed on the suture welding device so as to be translatable in a longitudinal direction to move the first and

second lengths of suture into contact with at least one electrode. Fenton teaches a fusible collar that encircles the sutures. Jaws 26 then compress the collar around the sutures. Fenton does not teach or suggest any structure that could form the claimed piston slidingly disposed on the suture welding device, or any structure that is translatable in a longitudinal direction to move the lengths of suture into contact with an electrode.

5. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 27 That the Suture Contacting Element is Configured to Force the First and Second Lengths of Suture into Close Physical Contact

Claim 27 recites that the suture contacting element is configured to force the first and second length of suture into close physical contact. Fenton's suture contacting element is the fusible collar 1, which encircles the sutures. However, the fusible collar 1 does not force the first and second lengths of suture into close physical structure. The fusible collar 1 does not supply any force to the sutures. Force is supplied by the jaws 26, which "compresses the collar 1 around the sutures 13." Fenton at Col. 7, lines 56-57. Thus, Fenton does not disclose a suture contacting element that is configured to force lengths of suture into close physical contact.

6. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 28 That the Suture Contacting Element Has at Least One Pod Configured to Prevent the First and Second Sutures from Sliding Off the Suture Contacting Element

Claim 28 recites that the suture contacting element has at least one pod configured to prevent the first and second sutures from sliding off the suture contacting element. As shown in FIG. 2A of the present application, reproduced below, the pods 172, 174 are specific structures that prevent the sutures from sliding off the suture contacting element.

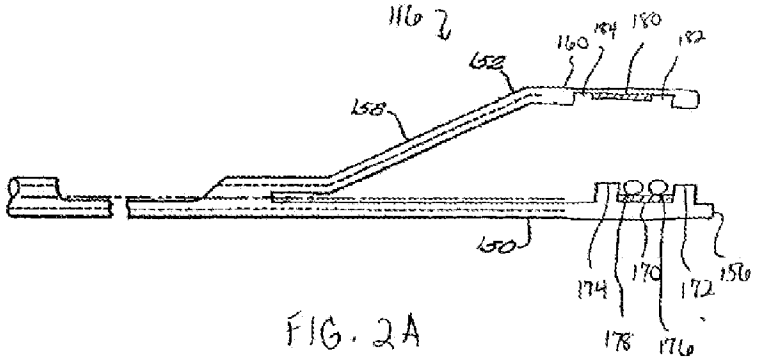

FIG. 2A

The Examiner argues that "'a suture contacting element' could be any portion of the collar [of Fenton] that contacts the suture, while the pod is the remaining portion of the collar that forms a pod like shape for holding the suture." *See* Advisory Action, March 19, 2007. However, as shown in FIG. 2A of Fenton, reproduced below, no portion of the collar forms a pod. The collar is simply a "ring-like structure" that "encircles" the sutures 13. *See* Fenton, Col. 4, lines 56-60.

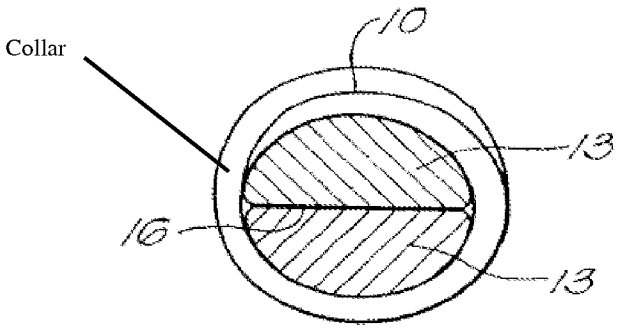

FIG. 2A

The Examiner never identifies the pod and none are apparent.

B. Neither Fenton nor Hulka Teaches or Suggests All the Elements Recited by the Claim 29 "System" Group of Claims

Neither Fenton nor Hulka teaches or suggests all the features of independent system claim 29. Claim 29 recites a suture welding device including a suture contacting element having at least one pod configured to prevent the first and second sutures from sliding off the suture contacting element. A first electrode is disposed on the suture contacting element for providing electrosurgical energy to weld the first and second lengths of suture into a fixed attachment. Claim 29 is similar in many respects to claim 1 except that (1) claim 29 recites electrosurgical energy rather than radio-frequency electrosurgical energy as recited in claim 1; (2) claim 29 does not positively recite the first and second lengths of suture; and (3) claim 29 recites the provision of at least one pod on the suture contacting element to prevent the sutures from sliding off the suture contacting element as is recited in claim 28.

1. Fenton Fails to Disclose, Teach or Suggest the Recitations of Claim 29 of a Suture Contacting Element Disposed on the Working End of a Suture Welding Device That Has at Least One Pod Configured to Prevent the First and Second Sutures from Sliding Off the Suture Contacting Element or Electrodes for Providing Energy to Weld First and Second Lengths of Suture

Claim 29 recites, *inter alia*, a suture welding system for fixedly attaching a first length of suture to a second length of suture at a suture welding site. The suture contacting element includes:

- at least one pod configured to prevent the first and second sutures from sliding off of the suture contacting element
- a first electrode . . . for providing electrical energy to the first and second lengths of suture
- a second electrode . . . for providing a return electrical energy path
- wherein provision of electrical energy by the first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment

Neither Fenton, nor Hulka, nor their combination, discloses, teaches or suggests this combination.

a. Fenton Fails to Disclose, Teach or Suggest the Recitations of Claim 29 Because Nowhere Does Fenton Teach or Suggest a Suture Contacting Element Disposed on the Working End of A Suture Welding Device That Has at Least One Pod Configured to Prevent the First and Second Sutures from Sliding Off the Suture Contacting Element

Fenton does not disclose, teach or suggest the recitations of claim 29. As discussed above with respect to claim 28, the pods of the present invention are specific structures that prevent the sutures from sliding off the suture contacting element. The Examiner argues that "'a suture contacting element' could be any portion of the collar [of Fenton] that contacts the suture, while the pod is the remaining portion of the collar that forms a pod like shape for holding the suture." *See* Advisory Action, March 19, 2007. However, no portion of the collar of Fenton forms a pod. The collar is simply a "ring-like structure" that "encircles" the sutures 13. *See* Fenton, Col. 4, lines 56-60. There is nothing on Fenton's ring that can be characterized as a pod.

b. Fenton Does Not Disclose, Teach or Suggest Suture Welding System of Claim 29 Because it Does Not Disclose Electrodes for Providing Energy to Weld First and Second Lengths of Suture

Fenton does not disclose, teach or suggest the recitations of claim 29, and in particular, Fenton does not teach a suture welding device with electrodes disposed on the suture contacting element for providing energy to weld first and second lengths of suture. As discussed above with respect to claim 1, Fenton's welding horn 25 melts the fusible collar 1 to bind sutures together. According to the Examiner, provision of energy to the working end of the device, and into the collar 1, causes the sutures to fuse together. To provide the "electrodes" recited in claim 29, the Examiner modifies, citing Hulka, the jaws 26 to be "electrodes."

Despite the Examiner's proposed modifications, Fenton still fails to disclose, teach or suggest providing energy to the lengths of sutures to weld them together. Hulka fails to fill this gap. Hulka provides a coaptation clamp device that delivers energy only to tissue. Such devices are well known and are recognized by numerous patents cited in the prosecution of the present application. No portion of the Hulka device contacts sutures, sutures are never disposed on the device, and energy is not delivered to sutures. Claim 29 recites a first electrode disposed on the suture contacting element for providing electrical energy to ***weld the first and second lengths of suture into a fixed attachment***.

In contrast, Fenton only discloses sutures that are wrapped in a fusible collar for loading into an ultrasonic welding device. The Examiner asserts that "the collar 1 is being interpreted as the suture contacting element, which is disposed on the working end 26 during use." However, as explained at col. 4, lines 30-33 of Fenton, the collar 1 is entirely separate from the fusing tool 20 that is used to compress and fuse the collar 1 around the sutures.

As with claim 1, ***Fenton only discloses applying energy to the collar – never to the suture*** as is required by the present claims.

c. Hulka Fails to Fill In the Gaps of Fenton Regarding Claim 29 Because No Portion of the Hulka Device Contacts Sutures, Sutures are Never Disposed on the Device and RF Energy is Not Delivered to Sutures.

Hulka does not disclose, teach or suggest the recitations of claim 1. Hulka provides a coaptation clamp device that delivers RF energy only to tissue. Such devices are well known and are recognized by numerous patents cited in the prosecution of the present application. No portion of the Hulka device contacts sutures (or provides a "pod" to prevent the sutures from sliding off of the suture contacting element), sutures are never disposed on the device, and RF energy is not delivered to sutures.

d. The Combination of Fenton and Hulka Does Not Provide the System of Claim 29

The Examiner argues that "'a suture contacting element' could be any portion of the collar [of Fenton] that contacts the suture, while the pod is the remaining portion of the collar that forms a pod like shape for holding the suture." *See* Advisory Action, March 19, 2007. However, as shown in FIG. 2A of Fenton, reproduced below, no portion of the collar forms a pod. The collar is simply a "ring-like structure" that "encircles" the sutures 13. *See* Fenton, Col. 4, lines 56-60.

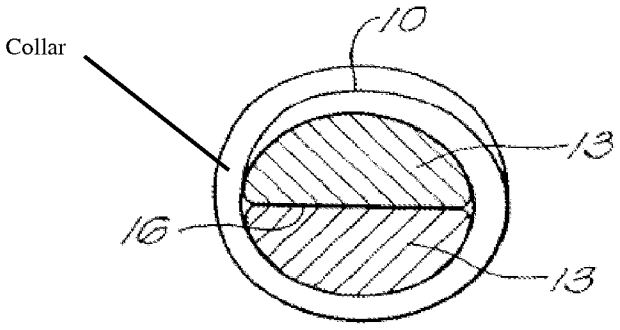

FIG. 2A

Adding Hulka merely results in applying electrical energy to the collar – it does not add a pod and it does not result in electrical energy being applied to the sutures to weld them together.

2. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 30 That the Electrosurgical Energy Source Generates Radio Frequency Waves for the Same Reasons That it Does Not for Claim 1

Claim 30 recites that the electrosurgical energy source generates radio frequency waves. Claim 30 is not anticipated by Fenton for the same reasons discussed above with respect to claim 1 regarding radio frequency energy applied to sutures. As noted above, cited RF energy references relate only to cutting and cauterizing of tissue. Fenton makes the leap of referring to RF in the context of "welding" – but only by application to a fusible collar that is specifically designed for that purpose.

3. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 31 That the Suture Contacting Element Comprises Two Opposing Faces Having a Variable Gap Therebetween, Each Face of the Suture Contacting Element Having an Electrode Disposed Thereon for the Same Reasons That it Does Not for Claim 3

Claim 31 recites that the suture contacting element comprises two opposing faces having a variable gap therebetween, each face having an electrode disposed thereon. The variable gap in claim 31 is not anticipated by Fenton for all of the reasons that claim 3 is not anticipated.

4. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 33 That the Suture Contacting Element is Configured to Force the First and Second Lengths of Suture into Close Physical Contact

Claim 33 recites that the suture contacting element is configured to force the first and second length of suture into close physical contact. Fenton's suture contacting element is the fusible collar 1, which encircles the sutures. However, the fusible collar 1 does not force the first and second lengths of suture into close physical contact. The fusible collar 1 does not supply any force to the sutures. Force is supplied by the jaws 26, which "compresses the collar 1 around the sutures 13." Fenton at Col. 7, lines 56-57. Thus, Fenton does not disclose a suture contacting element that is configured to force lengths of suture into close physical contact.

5. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 34 That the First and Second Lengths of Suture are Made of

Polydioxanone for the Same Reasons That it Does Not for Claims 5 and 6

Claim 34 recites that the first and second lengths of sutures to be welded are made from polydioxanone. Claim 34 is not anticipated by Fenton for the same reasons that welding of polydioxanone sutures is not anticipated with respect to claims 5 and 6.

C. Neither Fenton nor Hulka Teaches or Suggests All the Steps Recited by the Claim 20 "Method" Group of Claims

Neither Fenton nor Hulka teaches or suggests all the steps of independent method claim 20. Claim 20 recites a method for welding a first length of suture to a second length of suture including placing a first length of suture and a second length of suture into contact with a suture contacting element; and providing energy from the electrosurgical energy source through the first electrode to the first and second lengths of suture to weld the first length of suture to the second length of suture to create a fixed attachment therebetween.

1. Fenton Fails to Disclose, Teach or Suggest the Recitations of Claim 20 Because Nowhere Does Fenton Disclose, Teach or Suggest Placing Lengths of Suture into Contact With a Suture Contacting Element of a Suture Welding Device That Has Two Opposing Faces Having a Variable Gap Therebetween, Each Face Having Electrodes Disposed Thereon, and Providing Energy from the Electrosurgical Energy Source Through the First Electrode to the First and Second Lengths of Suture to Weld the First Length of Suture to the Second Length of Suture to Create a Fixed Attachment Therebetween

Applicant's claim 20 recites, *inter alia*, a ***method*** for welding a first length of suture to a second length of suture to create a fixed attachment therebetween. Because this independent claim recites a method, the interrelationship between the elements are recited as actions, making the arguments for method claim 20 even stronger than those made above for claim 1. Claim 20 recites:

- providing a suture welding device having:
  - a suture contacting element
  - a first electrode . . . disposed on the suture contacting element for providing electrical energy to the first and second lengths of suture
  - a second electrode . . . . for providing a return electrical energy path

- placing a first length of suture and a second length of suture into contact with the suture contacting element

- providing energy from the electrosurgical energy source through the first electrode to the first and second lengths of suture to weld the first length of suture to the second length of suture

Each and every argument provided with respect to claim 1 above applies with equal or greater force to claim 20 which recites action where the system claim of claim 1 recites structure and function.

a. In Addition, Fenton does not Disclose or Suggest a Suture Contacting Element of a Suture Welding Device That Has Two Opposing Faces Having A Variable Gap Therebetween, Each Face of the Suture Contacting Element Having an Electrode Disposed Thereon For at Least the Reasons that it Does Not for Claims 3 and 31.

Beyond the arguments provided with respect to claim 1, Claim 20 further recites that the suture contacting element has two opposing faces with a variable gap therebetween, each face having an electrode disposed thereon. The step of providing the suture contacting element having a variable gap in claim 20 is not anticipated by Fenton for all of the reasons that claims 3 and 31 are not anticipated. Combining the energy source of Hulka with Fenton does not cure these failings.

2. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 21 That the Sutures are Welded by Radio Frequency Waves Generated by the Electrosurgical Energy Source for the Same Reasons That it Does Not for Claims 1 and 30

Claim 21 recites that the electrosurgical energy source generates radio frequency waves. Claim 21 is not anticipated by Fenton for the same reasons discussed above with respect to claims 1 and 30 regarding radio frequency energy applied to sutures.

3. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 23 That the Lengths of Suture Are Constrained Within The Variable Gap of The Suture Welding Device for the Same Reasons That it Does Not for Claims 20 and 31

Claim 23 recites a variable gap as recited in claims 20 and 31. The step of providing the suture contacting element in claim 23 is not anticipated by Fenton for all of the reasons that claims 20 and 31 are not anticipated.

4. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 24 That the Suture Contacting Element Forces the First and Second Lengths of Suture into Close Physical Contact for the Same Reasons That it Does Not for Claim 33

Claim 24 recites that the suture contacting element is configured to force the first and second length of suture into close physical contact. Claim 24 is not anticipated by Fenton for the same reasons that the suture contacting element recited in claim 33 is not anticipated.

5. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 25 That the Suture Contacting Element Has at Least One Pod Configured to Prevent the First and Second Sutures from Sliding Off the Suture Contacting Element for the Same Reasons That it Does Not for Claim 28

Claim 25 recites that the suture contacting element has at least one pod configured to prevent the first and second sutures from sliding off the suture contacting element. Claim 25 is not anticipated by Fenton for the same reasons that the at least one pod configured to prevent the first and second sutures from sliding off the suture contacting element in claim 28 is not anticipated.

6. Fenton Fails to Disclose, Teach or Suggest the Additional Recitations of Claim 26 That the First and Second Lengths of Suture are Made of Polydioxanone for the Same Reasons That it Does Not for Claims 5, 6 and 34

Claim 26 recites that the first and second lengths of sutures to be welded are made from polydioxanone. Claim 26 is not anticipated by Fenton for the same reasons that welding of polydioxanone sutures is not anticipated with respect to claims 5, 6, and 34.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

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CLAIMS APPENDIX

1. (Previously Presented) A suture welding system for fixedly attaching a first length of suture to a second length of suture at a suture welding site, comprising:

an electrosurgical energy source configured to generate radio frequency waves;

first and second lengths of suture; and

a suture welding device, having:

a working end;

a suture contacting element located on the working end and having the first and second lengths of suture disposed thereon;

a first electrode electrically coupled to the electrosurgical energy source and disposed on the suture contacting element for providing radio frequency energy to the first and second lengths of suture; and

a second electrode electrically coupled to the electrosurgical energy source and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source;

wherein provision of radio frequency energy by the first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment.

2. (Canceled)

3. (Original) The system according to claim 1 wherein the suture contacting element comprises two opposing faces having a variable gap therebetween, each face having an electrode disposed thereon.

4. (Original) The system according to claim 3 wherein the suture welding device is configured to be selectively adjustable between an open position and a closed position, wherein the first and second lengths of suture may be placed within the variable gap in the open position and wherein the lengths of suture are constrained within the variable gap in the closed position.

5. (Original) The system according to claim 1 wherein the first and second lengths of suture are made of material selected from the group consisting of polydioxanone, prolene, and polymer plastics.

6. (Original) The system according to claim 1 wherein the first and second lengths of suture are made of polydioxanone.

7. (Previously Presented) The system according to claim 1 wherein a weldable material is provided between at least one electrode and at least one length of suture, the weldable material adapted to weld the first length of suture thread to the second length of suture thread upon application of radio frequency energy through the at least one electrode.

8. (Previously Presented) The suture welding device of claim 1,

wherein the suture welding device includes a piston slidingly disposed on the suture welding device so as to be translatable in a longitudinal direction to move the first and second lengths of suture into contact with at least one electrode.

9-19. (Canceled)

20. (Previously Presented) A method for welding a first length of suture to a second length of suture to create a fixed attachment therebetween, comprising:

(a) providing an electrosurgical energy source;

(b) providing a suture welding device, having:

a working end;

a suture contacting element disposed on the working end, the suture contacting element having two opposing faces having a variable gap therebetween, each face having an electrode disposed thereon;

a first electrode electrically coupled to the electrosurgical energy source and disposed on the suture contacting element for providing electrical energy to the first and second lengths of suture; and

a second electrode electrically coupled to the electrosurgical energy source and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source;

(c) placing a first length of suture and a second length of suture into contact with the suture contacting element; and

(d) providing energy from the electrosurgical energy source through the first electrode to the first and second lengths of suture to weld the first length of suture to the second length of suture to create a fixed attachment therebetween.

21. (Previously Presented) The method of claim 20 wherein the electrosurgical energy source generates radio frequency waves.

22. (Canceled)

23. (Previously Presented) The method of claim 22 wherein the suture welding device is configured to be selectively adjustable between an open position and a closed position, wherein the first and second lengths of suture may be placed within the variable gap in the open position and wherein the lengths of suture are constrained within the variable gap in the closed position.

24. (Previously Presented) The method of claim 23 wherein the suture contacting element forces the first and second lengths of suture into close physical contact with each other when the suture welding device is placed in the closed position.

25. (Previously Presented) The method of claim 20 wherein the suture contacting element has at least one pod configured to prevent the first and second sutures from sliding off of the suture contacting element.

26. (Previously Presented) The method of claim 20 wherein the first and second lengths of suture are made from polydioxanone.

27. (Previously Presented) The system of claim 4 wherein the suture contacting element is configured to force the first and second length of suture into close physical contact when the suture welding device is placed in the closed position.

28. (Previously Presented) The system of claim 1 wherein the suture contacting element has at least one pod configured to prevent the first and second sutures from sliding off of the suture contacting element.

29. (Previously Presented) A suture welding system for fixedly attaching a first length of suture to a second length of suture at a suture welding site, comprising:

an electrosurgical energy source; and

a suture welding device, having:

a working end;

a suture contacting element disposed on the working end, the suture contacting element having at least one pod configured to prevent the first and second sutures from sliding off of the suture contacting element;

a first electrode electrically coupled to the electrosurgical energy source and disposed on the suture contacting element for providing electrical energy to the first and second lengths of suture; and

a second electrode electrically coupled to the electrosurgical energy source and disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source;

wherein provision of electrical energy by the first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment.

30. (Previously Presented) The system of claim 29 wherein the electrosurgical energy source generates radio frequency waves.

31. (Previously Presented) The system of claim 29 wherein the suture contacting element comprises two opposing faces having a variable gap therebetween, each face having an electrode disposed thereon.

32. (Previously Presented) The system of claim 31 wherein the suture welding device is configured to be selectively adjustable between an open position and a closed position, wherein the first and second lengths of suture may be placed within the variable gap in the open position and wherein the lengths of suture are constrained within the variable gap in the closed position.

33. (Previously Presented) The system of claim 32 wherein the suture contacting element is configured to force the first and second length of suture into close physical contact when the suture welding device is placed in the closed position.

34. (Previously Presented) The system of claim 29, wherein the first and second lengths of suture are made of polydioxanone.

EVIDENCE APPENDIX

No evidence has been submitted.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

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